

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

3121. Misbranding of penicillin sodium. U. S. v. 696 Cartons, etc. (F. D. C. No. 23191. Sample Nos. 64198-H, 64199-H.)

LABEL FILED: June 18, 1947, Southern District of New York.

ALLEGED SHIPMENT: On or about May 13, 1947, by Barich, Inc., from East Rutherford, N. J.

PRODUCT: 696 cartons, each containing 5 200,000-unit vials, and 9 cartons, each containing 5 500,000-unit vials, of *penicillin sodium* at New York, N. Y.

LABEL, IN PART: (Cartons) "Penicillin Sodium Proctor * * * Proctor Laboratories 475 Fifth Avenue New York 17, U. S. A."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was misleading since it failed to reveal the fact that Proctor Laboratories was not the manufacturer of the article, which fact was material in the light of the unmodified words "Proctor Laboratories" appearing in the labeling; and the label statements "Lot No. 77 * * * Oct-1-48" on the 200,000-unit vials and "Lot No. 90 * * * Oct 1 1948" on the 500,000-unit vials were misleading since they represented and suggested that the article had been certified under such identifying marks in accordance with regulations promulgated by the Federal Security Administrator, whereas the article had not been so certified.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (1), the article was represented as a drug composed wholly of *penicillin sodium*, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law.

DISPOSITION: June 1, 1950. The Proctor Laboratories having appeared as claimant and subsequently having withdrawn its claim, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3122. Misbranding of amytal tablets. U. S. v. Cosmopolitan Drug Co. and Charles M. Berman. Pleas of nolo contendere. Fine of \$100 and costs against company; fine of \$50 against individual. (F. D. C. No. 28103. Sample Nos. 42324-K, 43185-K, 43189-K.)

INFORMATION FILED: January 17, 1950, Northern District of Illinois, against the Cosmopolitan Drug Co., a partnership, Chicago, Ill., and Charles M. Berman, a pharmacist for the partnership.

INTERSTATE SHIPMENT: Between the approximate dates of October 20 and November 17, 1948, from the State of Indiana into the State of Illinois.

ALLEGED VIOLATION: On or about February 17, 18, and 23, 1949, while a number of *amytal tablets* were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the tablets to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged tablets being misbranded.

*See also No. 3121.